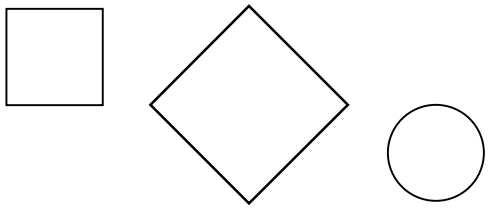
Breast Diagnostic Algorithms For Primary Care Clinicians



Clinical Breast Protocols Workgroup

May 2000
Revised Second Edition

California Department of Health Services, Cancer Detection Section
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www.sdsu.edu/qap

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Background and Acknowledgments

Breast Diagnostic Algorithms for Primary Care Clinicians is the product of the Clinical Breast Protocols Workgroup (Workgroup), an expert panel of volunteer California clinicians. Using the breadth and depth of each member's expertise, the Workgroup provides ongoing consultation on clinical issues to the Cancer Detection Section (CDS) in the Cancer Control Branch of the California Department of Health Services (CDHS).

CDS manages the state-funded Breast Cancer Early Detection Program (BCEDP), along with the federally-funded Breast and Cervical Cancer Control Program (BCCCP). These programs help eligible underserved, low-income women fight breast cancer by providing patient and provider education and screening and diagnostic services free of charge.

The algorithms were originally published in 1997 and placed on a UC Davis website. This second edition represents updates and revisions that incorporate new guidelines, research, and technologies, especially the use of ultrasound and interpretation of pathology. The algorithms have been renumbered and resequenced with the addition of the work-up of a clinically suspected cyst. They are now posted on the website: www.sdsu.edu/qap. Periodic updates will be posted to this website.

Clinical Breast Protocols Workgroup Members

Over the years some of the Workgroup members have changed, so their contributions are noted by the editions they developed (1997 or 2000). Workgroup members played significant authorship roles for content development and formatting.

- Lawrence D Wagman, MD, Chairman, Division of Surgery, and Director, Department of General Oncologic Surgery, City of Hope National Medical Center, Duarte, CA (Workgroup Chairman, 1997 and 2000)
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- Robyn Birdwell, MD, Assistant Professor of Radiology, Stanford University Hospital, Stanford, CA (2000)
- Charles Elboim, MD, General Surgeon, Sonoma, CA (2000)
- Patricia Ganz, MD, Division of Cancer Control, UCLA School of Medicine and Public Health, Los Angeles, CA (1997 and 2000)
- Lydia Howell, MD, Department of Pathology, UC Davis Medical Center, Sacramento, CA (1997 and 2000)
- Joy Melnikow, MD, Department of Family Practice, UC Davis Medical Center, Sacramento, CA (1997)
- Julie Ohnemus, MD, Family Practitioner, Arcata, CA (2000)
- Greg Talavera, MD, Family Practitioner, Department of Family and Preventive Medicine, UCSD and Graduate School of Public Health, SDSU, San Diego, CA (1997 and 2000)

CDS acknowledges and appreciates the voluntary contributions of these Workgroup members and of the many California-based clinicians who participated in the review phase/field test of this document.

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Intended Audience

The intended users of these algorithms are primary care clinicians who provide breast cancer screening and diagnostic services in Cancer Detection Section programs. Primary care clinicians are recognized as being key to ensuring that women receive timely screening and diagnostic services, including follow-up and referral to other breast cancer service providers and specialists. Clear oral and written communication between the primary care provider and the patient, as well as between the provider and radiologist and/or other breast specialist is crucial to management of breast abnormalities. Prompt evaluation and timely discussion of results will decrease women's anxiety levels and facilitate referrals for follow-up. Many women are at risk for failing to follow screening and rescreening guidelines, or to complete necessary services for diagnosis and treatment. These women need additional support and case management from the primary care clinician. Only through early detection with regular screening and follow-up is breast cancer mortality impacted.

Each clinician is encouraged to apply these algorithms as appropriate to his or her clinical decision-making so that clients receive timely and appropriate services. As with all medical protocols and algorithms, they are intended to serve as an adjunct, not a replacement for clinical judgement applied to individual cases.

Comments

- The guidelines described here do not represent the only medically or legally acceptable approach, but rather are presented with the recognition that there are alternate and acceptable approaches. Deviations under appropriate circumstances do not necessarily represent a breach of a medical standard of care. New knowledge, new technologies, clinical or research data, and clinical experiences may provide sound reasons for alternative approaches, even though they are not described in this document. Use of algorithms or practice guidelines, and careful documentation and tracking, are important for continuity of care, risk management and reimbursement.

- This document may be copied with full acknowledgment of the source.

- Suggested citation: Clinical Breast Protocols Workgroup, California Department of Health Services. *Breast Diagnostic Algorithms for Primary Care Clinicians.* UC Davis. 2000.

- Users of the algorithms are requested to direct any written comments or inquiries about updates to:

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How to Read and Use the Algorithms

Clinical protocols provide a logical progression of activity in the work-up of a woman presenting with a breast symptom or with abnormal findings on breast cancer screening and diagnosis. These protocols are based on an informal consensus development process of the California Department of Health Services Clinical Breast Protocols Workgroup, comprised of experts in family practice and several specialties.

Primary care clinicians who perform clinical breast examinations and refer women for mammography may have questions about the sequence of steps to perform when breast abnormalities are detected. The algorithms provide a visual representation of decision points and processes in an initial care plan and when referral to a breast specialist for definitive diagnosis, staging and treatment is indicated. The term "breast specialist" rather than radiologist, surgeon, or oncologist is used because access to these specialists may vary in each community.

These algorithms provide a guide for managing nine sets of findings or test results in the diagnostic component of care. Clinicians are encouraged to adapt the algorithms to each particular patient situation. The algorithms also apply to women with special needs (e.g., "worried well", high risk for breast cancer, disabled or medically compromised) although they may need individual adaptations and referrals to specialists. The special cases or nuances that breast specialists manage are not presented in this document. The algorithms present work-ups for the following clinical or radiographic findings (1-7) and diagnostic procedures (8-9):

1. A new palpable breast mass in a premenopausal woman

2. A new palpable breast mass in a postmenopausal woman

3. A clinically suspected cyst

4. A new non-palpable mammographic lesion

5. A spontaneous, unilateral nipple discharge in a non-lactating woman

6. Breast skin changes/nipple retraction

7. Breast pain in a non-lactating woman

8. Management of fine needle aspiration biopsy results for breast lesions

9. Management of breast tissue biopsy results.

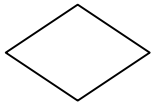
Each algorithm is accompanied by text that explains the work-up process, including relevant terminology, rationales, alternative approaches, and controversies. Readers should review this information prior to using the algorithm and then refer back to individual points as needed. The Appendix

contains definitions and additional terminology related to examinations and diagnostic test categories. A bibliography is included for readers who want additional information.

The following legend displays the graphic designations and abbreviations used in the algorithms:

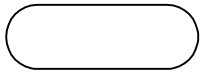
Graphic Designations

Starting point for algorithm



Decision

Process



Endpoint—decision finished for that algorithm

Connector to another page or algorithm

Notes

Abbreviations

CBE = Clinical Breast Examination

US = Ultrasound

FNAB = Fine Needle Aspiration Biopsy

F/U = Follow-up

DCIS = Ductal Carcinoma In Situ

ADH = Atypical Ductal Hyperplasia

NCI = National Cancer Institute

Work-up of a New Palpable Breast Mass in a Premenopausal and a Postmenopausal Woman

Management of the patient with a breast mass varies according to age, clinical history, and clinical findings. Detection of a breast mass usually creates significant anxiety in a woman and her family and requires sensitive provider/patient communication.

History and Physical Examination

Significant factors to be elicited in the woman's clinical history include: current symptoms such as nipple discharge, breast mass, change in mass with the menstrual cycle, mass in axilla, skin dimpling, ulceration, inflammation and non-cyclical pain; current medications, including hormonal therapy; history of previous breast cancer or other breast problems, especially biopsy showing atypical hyperplasia; history of breast implants or breast reduction; age at menarche and menopause; age at first live birth; exposure to radiation; history of trauma; family history of breast or ovarian cancer in a first degree relative (mother, sister, daughter); history of other types of cancer; and in the premenopausal woman, pregnancy and lactation history. Breast cancer screening history should include the date and results of the last clinical breast examination and mammography.

As part of the complete physical examination, the clinical breast exam (CBE) needs to be thorough and performed preferably during the first half of the woman's menstrual cycle. A comprehensive approach to CBE is included in the Appendix. Physical examination and mammography of the breasts of young premenopausal women can be challenging due to breast lumpiness from the increased glandular-to-fat ratio when compared to the more homogenous breasts of postmenopausal women.

Important questions to consider when assessing the index of suspicion for a breast lesion detected on physical examination include:

- Is it a symmetrical finding in both breasts?
- What is the consistency or texture?
- Is it mobile or fixed?
- What is the size and shape?
- Is it tender or non-tender?

Normal glandular tissue is generally mirrored in the contralateral breast. A discrete palpable mass is three dimensional, different from surrounding tissues and usually asymmetric. Clinical signs that are suggestive of benignity, but not diagnostic, include a mass that is soft or rubbery and mobile. Features suggestive of malignancy include a mass that feels firm or hard, has an irregular shape, is solitary, and feels different from surrounding breast tissue. Occasionally breast cancers are fixed and associated with other signs such as skin retraction.

Regardless of the age of a woman, every clinically suspicious lesion requires further evaluation. CBE is a method of detection, not an independent diagnostic test. A negative mammogram should not deter the clinician from follow-up; 15-18 percent of mammograms appear negative in the presence of a palpable cancer. Clinicians should, therefore, consider using the "triple test", CBE, mammography and Fine Needle Aspiration Biopsy (FNAB), described in the text for Algorithm 8. The triple test helps make a decision about whether to proceed with the work-up to avoid delay in the diagnosis and treatment of breast cancer.

New Palpable Mass in a Premenopausal Woman

If the clinician has any doubt about the nature of the mass, first consider a cyst. A cyst may be confirmed by ultrasound or by fine needle aspiration of cellular fluid (see Algorithm 3 for work-up of a clinically suspected cyst). Mammography in this age group is unreliable and ultrasound is a good alternative.

New Palpable Mass in a Postmenopausal Woman

Since the risk of breast carcinoma increases with age, clinicians need to be particularly suspicious of a dominant mass or asymmetric thickening in the breasts of postmenopausal women. Cystic findings become less common after menopause, although cysts, pain and discharge can be found in women taking hormone replacement therapy.

Diagnostic Mammography

Diagnostic mammography usually is the first-line investigation for a palpable mass in older women. However, if the clinician feels extremely confident that a mass is clinically benign (with the knowledge that benignity can only be established on tissue sampling), re-evaluating the woman in one to three months may be an option. This option requires that an excellent patient tracking system be in place, and the woman must be likely to return for the appointment.

The Mammography Quality Standards Act (MQSA) regulations require interpreting physicians to categorize the results of each mammogram using one of the terms (or equivalent wording) described in the radiologic definitions in the Appendix. The goal of the assessment category classification system is to make the reporting of mammographic results clearer and more consistent. These categories and similar terms also are used in BI-RADS™, the American College of Radiology's Breast Imaging Reporting and Data System.

Notes for Algorithms 1 and 2

Please note that wherever "mass resolved" directs the reader to "routine clinical follow-up and screening", this direction applies only when the rest of the exam is normal and there are no other symptoms. Otherwise the reader should go to the appropriate algorithm.

(1) Clinically benign masses such as fibroadenomas are classically rubbery and mobile. Prominent glandular tissue is generally mirrored in the contralateral breast. These signs are suggestive of benignity, but they are not diagnostic.

(2) A clinically suspicious mass may have one or more features consistent with cancer: feeling firm or hard, irregular, solitary, and different from the surrounding breast tissue. Sometimes such masses are fixed and associated with other signs such as skin retraction. However, any asymmetrical finding may be a cause for concern.

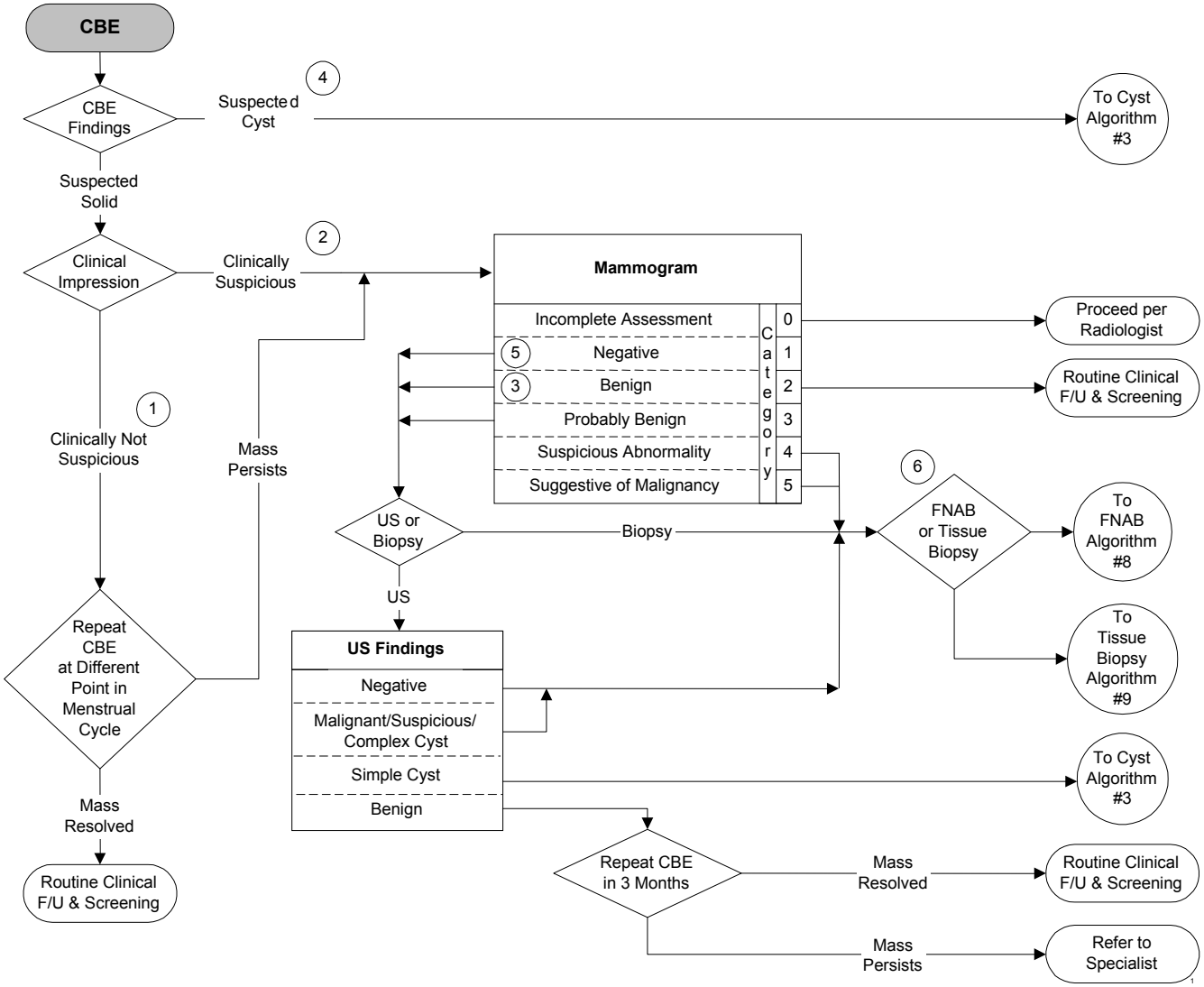
(3) Mammography can be performed using a radiopaque marker on the skin over a palpable lesion to help determine if the lesion corresponds to the mammographic lesion. A non-corresponding mammographic finding may represent a separate lesion which needs further work-up.

(4) When the clinician suspects that the mass is cystic, it is reasonable to proceed directly to aspiration in premenopausal women (or postmenopausal women who have had a mammogram within six months). Ultrasound is the imaging method of first choice in younger women <30 years of age. Ultrasound can help distinguish solid from cystic masses. However, even ultrasound has limitations in making this distinction. Mammography can be used to further define the mass, although mammograms in younger women can be difficult to interpret due to increased tissue density. Neither ultrasonography nor mammography are diagnostic of malignancy; malignancy can only be confirmed through FNAB cytology or tissue biopsy. FNAB implies cytological examination of the cells obtained by aspiration of the lesion (with several passes of the needle) using a fine needle (22 gauge or smaller). FNAB should be performed by health professionals trained and experienced in the technique.

(5) A negative mammogram should not deter the clinician from arranging FNAB or tissue biopsy of a palpable mass, since around 18 percent of mammograms are normal in the presence of a palpable cancer.

(6) FNAB is optional if another type of biopsy is planned. FNAB may assist in patient counseling and planning the surgical approach. However, a negative FNAB does not preclude proceeding with excisional biopsy/definitive surgery. See Algorithm 8 for managing results of FNAB and Algorithm 9 for managing results of tissue biopsy. If interpretation of the mammogram, CBE or FNAB are discordant (disagree), consider referring for tissue biopsy.

Work-up of a New Palpable Breast Mass in a Premenopausal Woman



California Department of Health Services, 2000.

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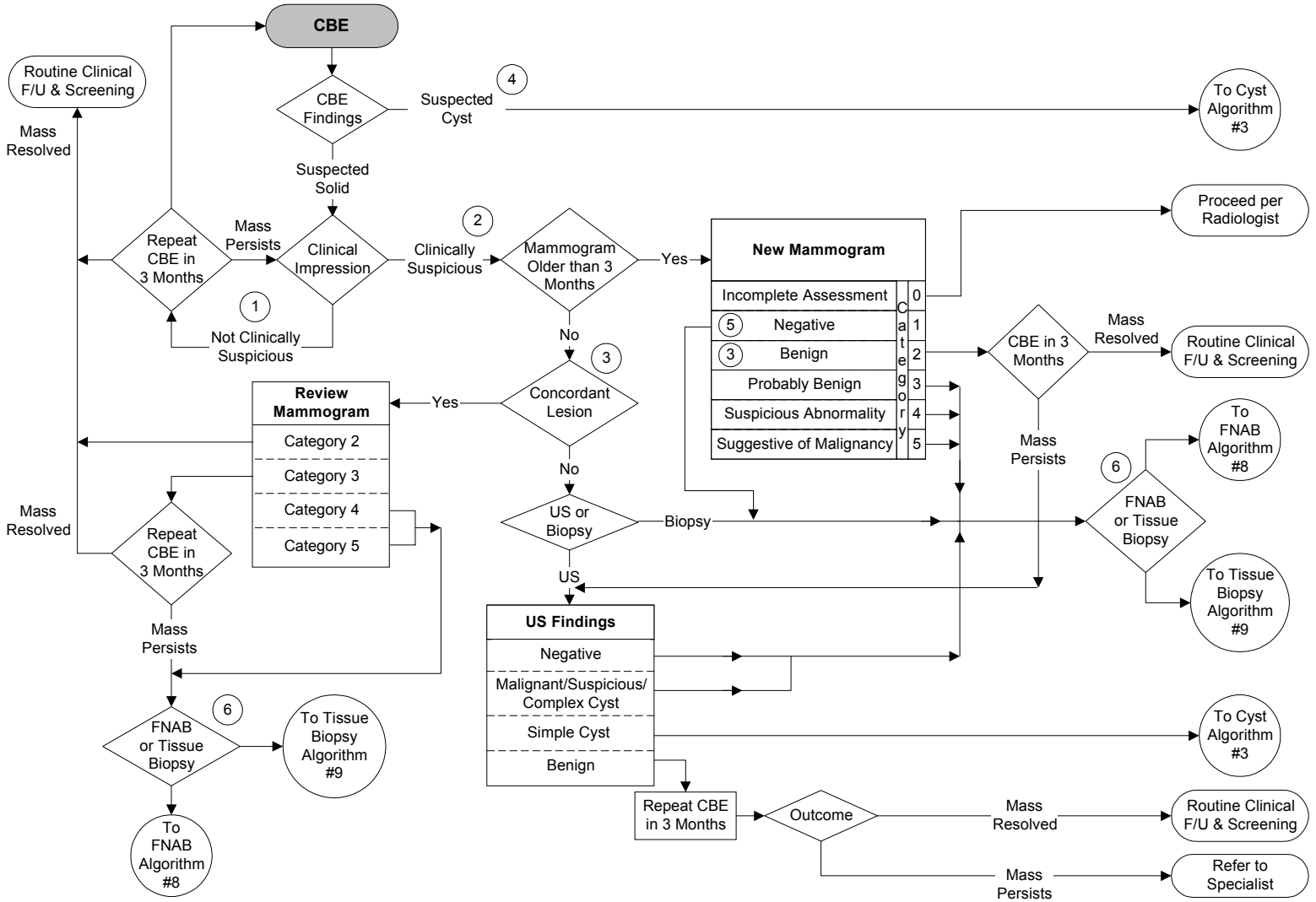
Work-up of a New Palpable Breast Mass in a Postmenopausal Woman



California Department of Health Services, 2000.

Work-up of a Clinically Suspected Cyst

Cysts are fluctuant, round or oblong, and vary in size. Ultrasonography depicts the fluid within cysts and can diagnose cysts as small as 2 to 3 mm in diameter in small breasts, but not as easily in large, fatty breast tissue. Simple cysts are characterized on ultrasound as fulfilling four criteria: round or oval, sharply defined margins, lack of internal echoes, and posterior acoustic enhancement. Simple cysts require only routine follow-up. Cysts with debris or thick material inside need to be aspirated for definitive diagnosis. Aspiration of a cyst can be guided by palpation, ultrasound or mammography. Non-palpable simple cysts detected by mammography and confirmed by ultrasound do not need to be aspirated except to relieve pain.

In a premenopausal woman, a cyst that is completely resolved by fine needle aspiration, revealing non-bloody fluid, can be considered insignificant if there are no signs of recurrence four to six weeks post-aspiration. Non-bloody cystic fluid should not routinely be sent for cytological analysis, as the incidence of cancer is less than one percent. A cyst that recurs more than two times within four to six weeks, displays bloody fluid, or leaves a residual palpable mass post-aspiration demands cytologic examination and further evaluation.

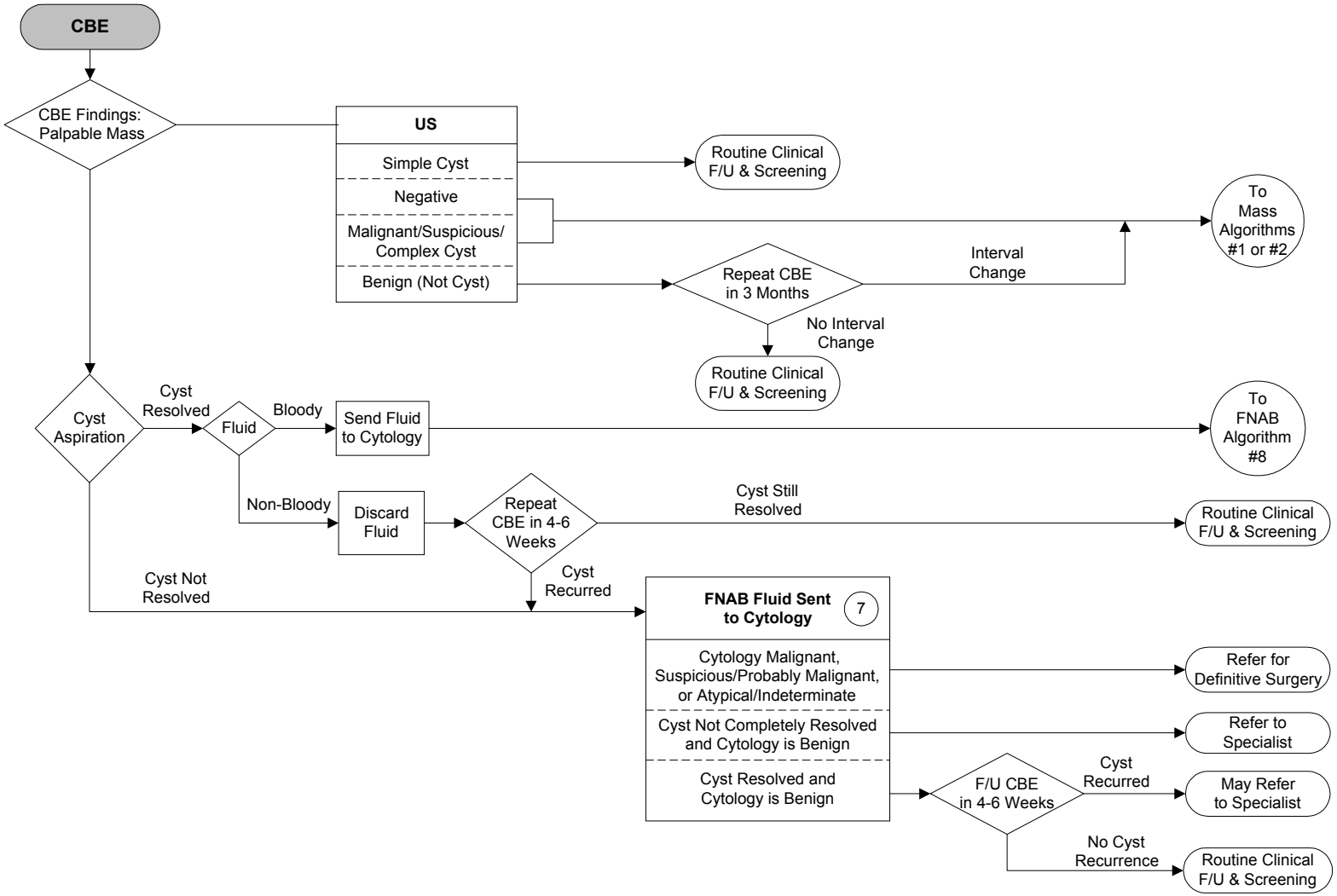
In the postmenopausal woman, cystic findings become less common. However, cysts can be found in older women, especially those on hormone replacement therapy.

Although multiple cysts commonly occur, the woman with breast cysts needs to be advised to be particularly cautious and to seek medical advice when a new mass arises. Neither the clinician nor the woman can automatically assume that a new mass is "just another cyst."

Notes for Algorithm 3

(7) FNAB implies cytological examination of the cells obtained by aspiration of the lesion using a fine needle (22 gauge or smaller). FNAB should be performed by health professionals trained and experienced in the technique. Likewise, cellular analysis should be interpreted by a pathologist skilled in cytological assessment. If the pathologist reports that the aspiration is inadequate for analysis, the FNAB should be repeated and another biopsy method considered. See further explanations accompanying Algorithm 8.

Work-up of a Clinically Suspected Cyst



California Department of Health Services, 2000.

Work-up of a New Non-Palpable Mammographic Lesion

The categories used to describe findings from a mammogram were outlined in Algorithms 1 and 2 and in the Radiologic Definitions in the Appendix. The four final assessment categories that relate to this algorithm include:

Category 2. Benign finding—routine screening schedule
Category 3. Probably benign finding — short interval follow-up suggested
Category 4. Suspicious abnormality — biopsy should be considered
Category 5. Highly suggestive of malignancy — appropriate action should be taken.

Non-palpable mammographic lesions are suspicious when they are 1) seen on two orthogonal views, 2) are ill defined, lobulated or spiculated, or 3) contain microcalcifications (usually 5 or 6). Radiologists should advise which image-guided procedures to use for obtaining tissue.

Routine clinical follow-up is appropriate for category 2, but categories 3, 4, and 5 always require further evaluation despite being clinically occult. A reasonable percentage of these lesions will be shown to be cancerous. In fact, it is the detection of these small or pre-invasive cancers by mammography that can significantly contribute to the reduction in breast cancer mortality. Ideally, further assessment of an abnormality detected on clinical breast examination and/or a multidisciplinary team, including a skilled radiologic technologist, radiologist, surgeon, and pathologist, should perform screening mammography. In settings where this cannot be accomplished within a single clinic, excellent communication should be maintained between the woman's primary care provider and the breast specialists.

A category 3 lesion generally will require clinical evaluation at the time of mammography and again within six months as recommended by a breast specialist. Some of these cases will be biopsied or excised, depending on the recommendations of the breast specialist and the preferences of the woman. Ultrasound may be used to guide further evaluation.

A category 4 lesion should lead to biopsy. If the lesion is definitively diagnosed as benign at core biopsy, and is consistent (concordant) with the radiological findings, excisional biopsy may not be required. This decision should only be made by the experienced assessment team.

Similarly, a category 5 lesion demands tissue diagnosis. The methods of biopsy include stereotactic/ultrasound-guided core biopsy to aid in treatment planning, or negative margin excisional biopsy after needle localization.

For lesions with mammography categories 3, 4, and 5 that may require stereotactic/ultrasound-guided biopsies, consultation with a surgeon, as well as a radiologist, is advisable. With rare exception, all mammograms with a category 4 or 5 result should lead to a tissue biopsy.

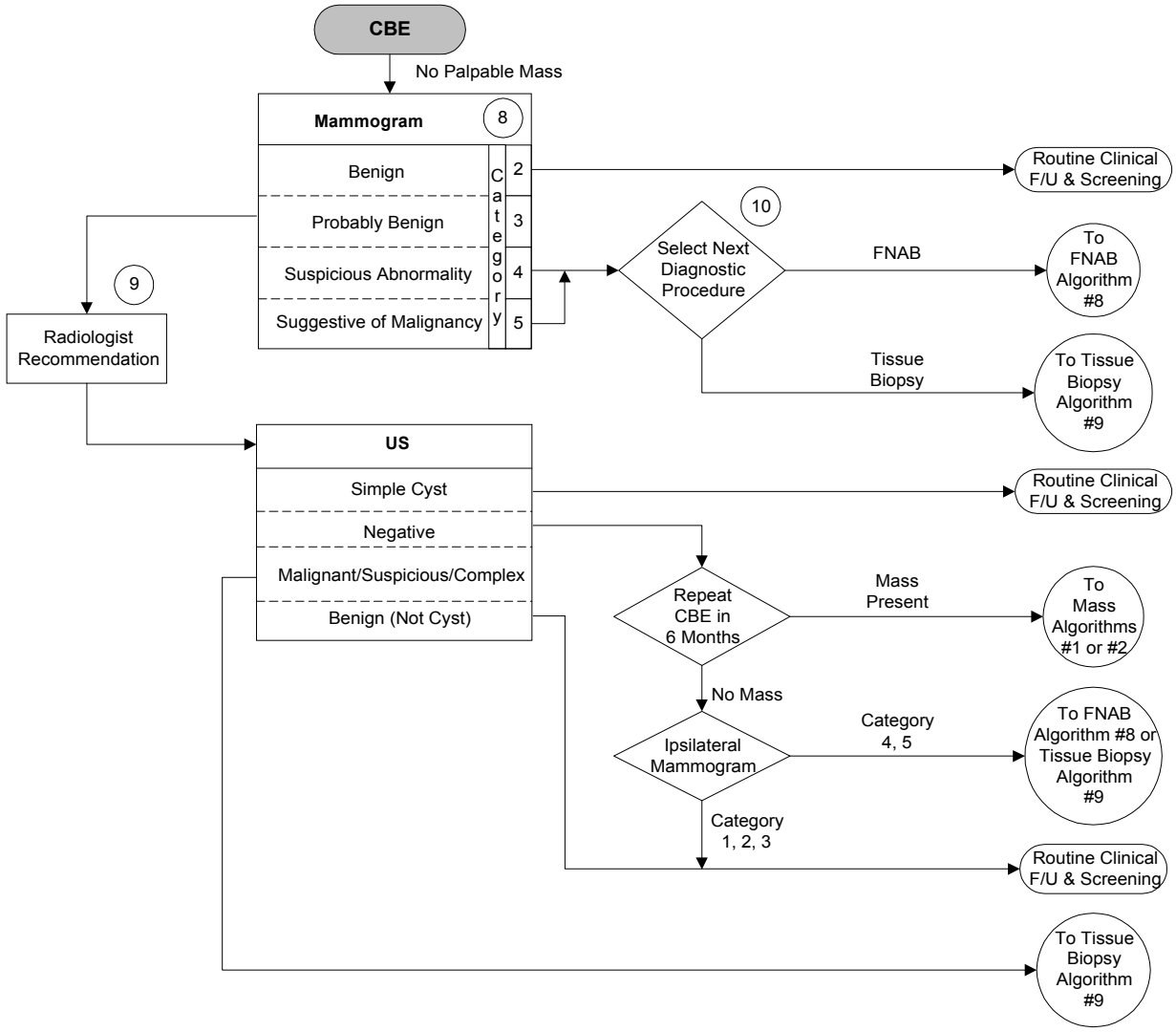
Following excision of non-palpable mammographic lesions, specimen radiography is used to confirm lesion excision.

8 Mammographically detected lesions may require "work-up" (diagnostic) views and ultrasound before being categorized 2 through 5.

9 A patient with a category 3 mammography result who is concerned and does not want to wait six months may need to be referred to a breast specialist.

10 An examining radiologist may prefer FNAB to core biopsy, recognizing the limitation that FNAB is unable to distinguish invasive from non-invasive carcinoma; this limitation could have treatment implications.

Work-up of a New Non-Palpable Mammographic Lesion



California Department of Health Services, 2000.

Work-up of Spontaneous, Unilateral Nipple Discharge in a Non-Lactating Woman

A true nipple discharge is one originating in one or more duct(s). Pseudo-nipple discharges can be caused by inverted nipples, eczema, infection, etc. The clinical history of the nipple discharge will usually define its origin. A true nipple discharge will likely be reported by the woman as having begun spontaneously (not in response to stimulation) and staining her bra, bed sheet or sleeping garment.

Important questions to consider in the work-up of nipple discharge include:

- Is the discharge unilateral or bilateral?
- What medications is the woman taking?
- Is she pregnant?
- Is the discharge spontaneous or expressible?
- Do single or multiple ducts appear to be involved?
- Is the discharge associated with a mass?
- What is the consistency of the discharge?
- What is the color of the discharge?

If a true unilateral, spontaneous discharge exists, it is highly unlikely to resolve without surgical intervention. Endocrine causes of galactorrhea include pregnancy, hypothyroidism and amenorrhea syndromes. Medications such as antihypertensives, oral contraceptives, phenothiazines, and tranquilizers may also cause nipple discharge.

Every woman with a unilateral, spontaneous, clear, serous, or bloody discharge should be referred for diagnostic mammography prior to surgical referral. A mammographic abnormality should correspond with the quadrant of the breast from which the discharge originates for it to be considered relevant to the cause of the discharge. Most mammograms in these instances, however, are normal and should not deter surgical referral.

The work-up of unilateral nipple discharge is described in Algorithm 5. Bilateral nipple discharges usually have physiological causes, such as hyperprolactinemia associated with infertility that may lead to galactorrhea, but can occur in breast disease that is bilateral, e.g., mammary duct ectasia. Mammary duct ectasia is a benign condition occurring in postmenopausal women, characterized by dilation of the ducts, nipple secretions and periductal inflammation.

A discharge from a single duct is of concern whether the discharge is clear/watery, serous or bloody. Multiple duct discharges are rarely caused by cancer.

Cytology in the assessment of nipple discharge is controversial and generally is not recommended as a first line investigation because it is associated with a high number of false results.

Notes for Algorithm 5

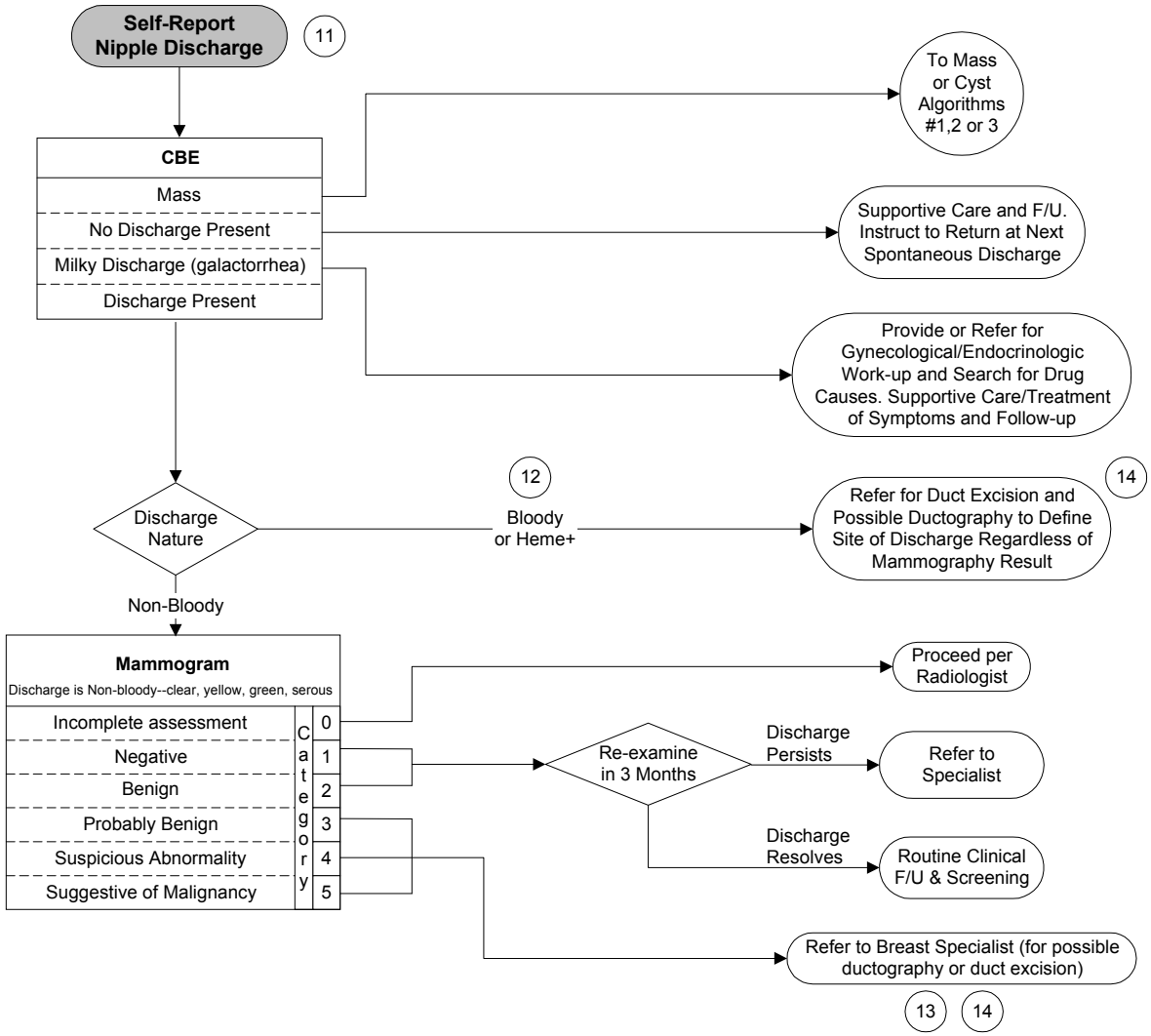
(11) A non-spontaneous discharge usually is normal. Thus it is more clinically relevant to elicit a history of a spontaneous discharge. The patient should be asked whether she has noticed staining of her clothing. A true nipple discharge originates in one or more duct(s). Pseudo-nipple discharges can be caused by inverted nipples, eczema, infection, etc.

(12) Heme + refers to a positive result on a Hemoccult test. Discharges can be tested for occult blood.

(13) The mammographic abnormality should correspond with the quadrant from which the discharge originates. (An abnormality that does not correspond to the quadrant may represent a separate lesion. Even a mammographic abnormality that corresponds to the palpable lesion might be a separate lesion, needing further work-up.)

(14) Ductography, also referred to as galactography, is a mammographic study that involves injection of water-soluble contrast into a duct. Ductography can be a guide to aid diagnosis and define the source (location) of the duct causing the nipple discharge. It may minimize the necessity for and size of surgical resection. Clinicians disagree about its utility and cost-effectiveness. Surgical and/or radiological consultation is recommended prior to embarking upon this procedure.

Work-up of Spontaneous Unilateral Nipple Discharge in a Non-Lactating Woman



California Department of Health Services, 2000.

Work-up of Breast Skin Changes/Nipple Retraction

A thorough history and examination are important in the assessment of the patient who is symptomatic of skin changes (such as scaling) or nipple retraction. Important questions to consider include:

- How long has the change been present?
- Is there an associated palpable mass or mammographic abnormality?
- Is it a unilateral finding?

Timing of onset is of paramount importance; longstanding (for many years) or bilateral nipple inversion is insignificant; recent or unilateral, even if slight, nipple retraction has more serious implications.

Skin changes that may signify carcinoma include skin redness, retraction, or dimpling; and nipple excoriation or crustiness. Asymmetry of the breasts that indicates a recent change or previous biopsy scars should also be noted, along with other signs, such as a mass. Signs of inflammation can be treated with a 10 day course of antibiotics that cover skin bacteria, including anaerobes (e.g., cephalexin plus metronidazole), but if unresponsive, inflammatory carcinoma must be excluded by further work-up. Nipple retraction can be managed in a similar manner (mixed flora has been cultured--aerobes and anaerobes--typical of those in the mouth and vagina) for possible periductal mastitis and deeper tissue infections. A lack of response requires further work-up.

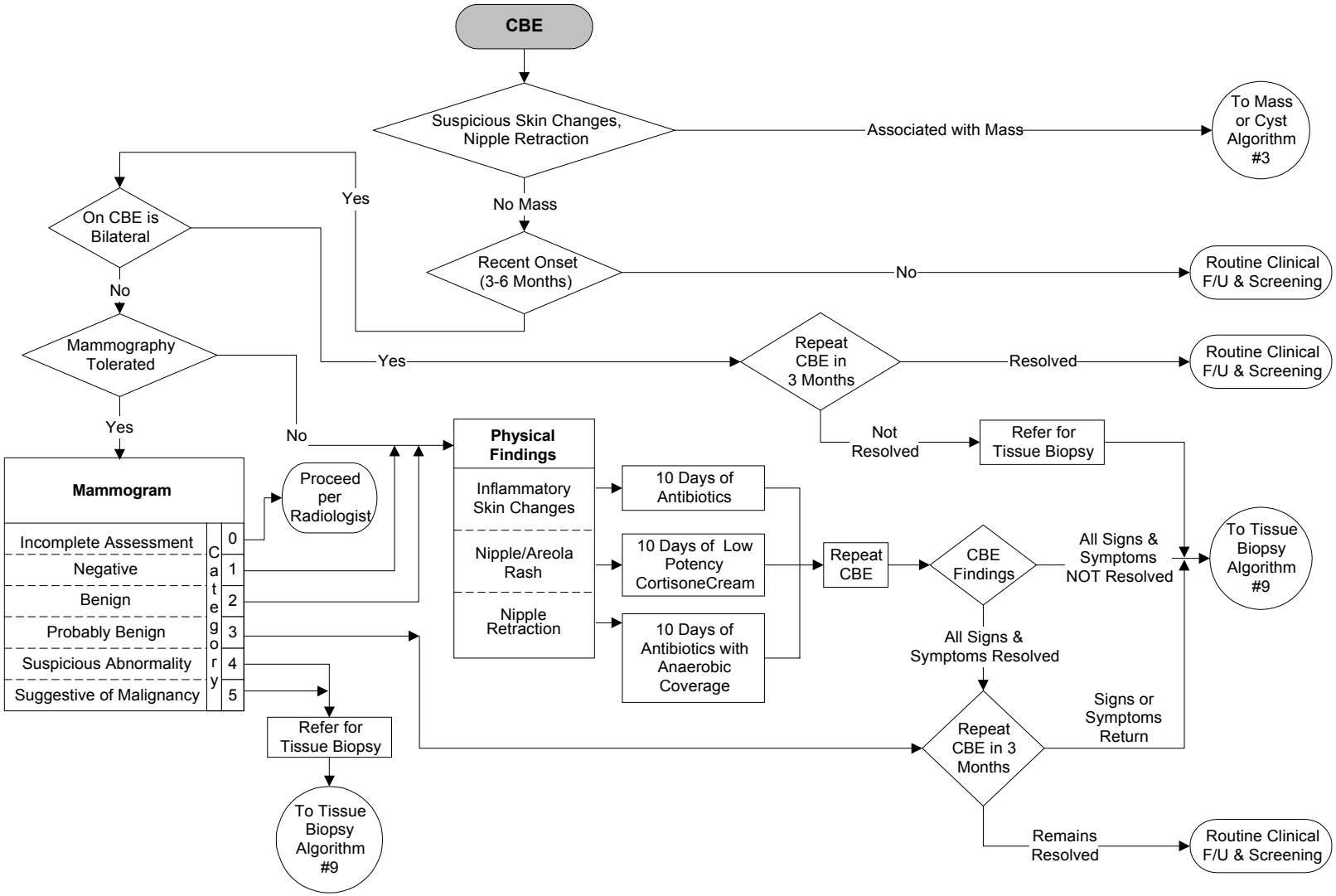
There are many dermatologic causes of red, oozing and crusted nipples, including psoriasis, seborrheic dermatitis, contact dermatitis, neurodermatitis and atopic dermatitis. Eczema may be localized or involve the complete nipple-areolar complex and must be distinguished from the non-eczema conditions of Paget's disease of the nipple.

Eczema	Paget's Disease of the Nipple
Usually bilateral	Unilateral
Intermittent history with rapid evolution	Continuous history with slow progression
Moist	Moist or dry
Indefinite edge	Irregular but definite edge
Nipple may be spared	Nipple always involved and disappears in advanced cases
Itching common	Itching common

From Hughes LE et al. *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London, Ballière Tindell, 1989.

Despite some of these clinical differences, it is important to consider Paget's disease until proven otherwise. Nipple scaling may respond to a short course of topical steroids, but this should not dissuade prompt referral to a breast specialist. Bilateral mammography is the first line investigation when there are breast skin or nipple changes, even if no mass is palpable on CBE. This is done to rule out non-palpable lesions. Mammography is often negative in these cases, but a negative mammogram must not preclude surgical referral.

Work-up of Breast Skin Changes/Nipple Retraction



California Department of Health Services, 2000.

Work-up of Breast Pain in a Non-Lactating Woman

Breast pain is a common symptom that usually is mild and in phase with the menstrual cycle. Important questions to consider:

- Is it cyclic or non-cyclic?
- Is the pain diffuse or focal?
- Is it bilateral or unilateral?
- Is it associated with a mass?
- Was hormone replacement therapy recently initiated?
- Is there a history of recent trauma?

Cyclic pain usually is normal in women before menopause or in postmenopausal women on hormone replacement therapy. Common causes of non-cyclic pain are a cyst or fibrocystic changes. The differential diagnosis of breast pain includes a normal physiological event, a hematoma, fat necrosis, a ruptured cyst, a non-ruptured cyst under tension, infection, a tumor, and an idiopathic condition. (This excludes chest wall pain.)

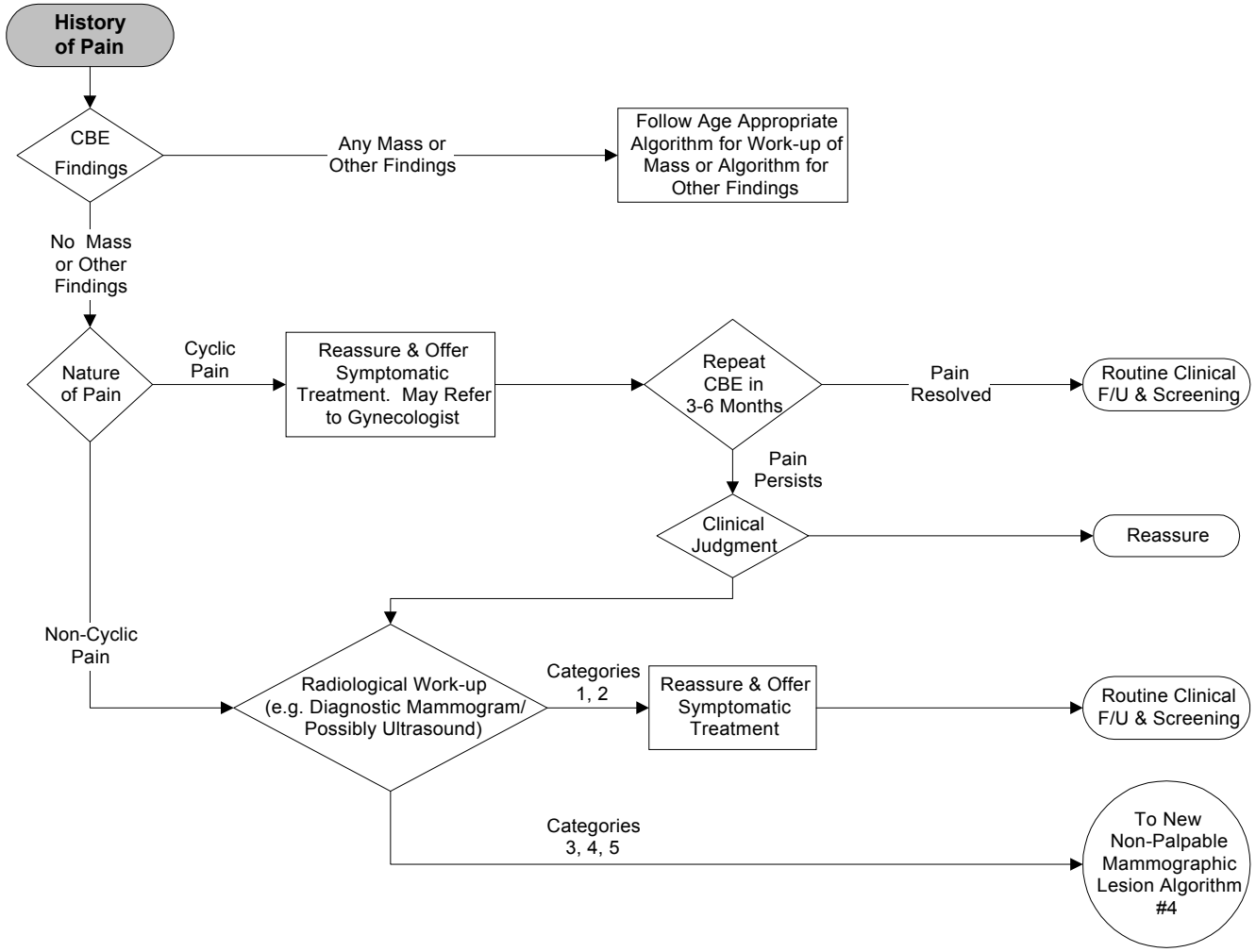
Non-cyclic pain is initially investigated with a bilateral mammogram. If the patient is a young woman then an ultrasound is preferred. For most women, treatment consists of relieving symptoms and reassuring the patient that there is no underlying carcinoma or other serious disorder. Non-narcotic analgesics and supportive bras can be helpful. Some women may find relief by using oil of primrose (3 grams a day). Elimination of caffeine, chocolate or salt from the diet has not been scientifically proven to be beneficial. Additional follow-up depends on the mammographic or ultrasound final assessment category.

Breast cancer is rarely associated with breast pain if there are no other signs or symptoms. A diagnosis of cancer must be considered in patients with well-localized breast pain of recent onset. The pain associated with breast cancer is often unilateral, persistent, and constant in position.

If there are changes consistent with mastitis (such as erythema, and fever > 102 degrees, skin tenderness, abscess, pus expressed from the nipple), treat with antibiotics for 10 days. If findings do not resolve, refer to Algorithm 5 on skin changes/nipple retraction.

Although this algorithm addresses the non-lactating woman, a similar work-up of breast pain in the lactating woman is recommended; but the latter may need referral to the woman's obstetrician/gynecologist or breast specialist as appropriate.

Work-up of Breast Pain in a Non-Lactating Woman



California Department of Health Services, 2000.

Management of Fine Needle Aspiration Biopsy (FNAB) Results for Breast Lesions

The term FNAB is used for a technique different from simple aspiration of a cyst. The technique involves an average of two to four needle passes into the lesion to obtain an adequate cellular sample for cytologic evaluation. More passes may be needed in certain situations. Although FNAB is quick and safe, it should be performed by a clinician experienced in the technique, and the slides should be sent to an expert cytopathologist for accurate results. Recommendations for training requirements and prerequisites for physicians performing FNAB are outlined in the 1997 NCI reference in the Bibliography.

FNAB with results suspicious for cancer may assist in patient counseling and planning of a surgical approach. However, a negative FNAB does not preclude proceeding with excisional biopsy/definitive surgery if clinical or mammographic findings are suspicious.

Radiologists generally prefer that the FNAB be performed after the mammogram because distortion of the image may result from any post-FNAB hematoma.

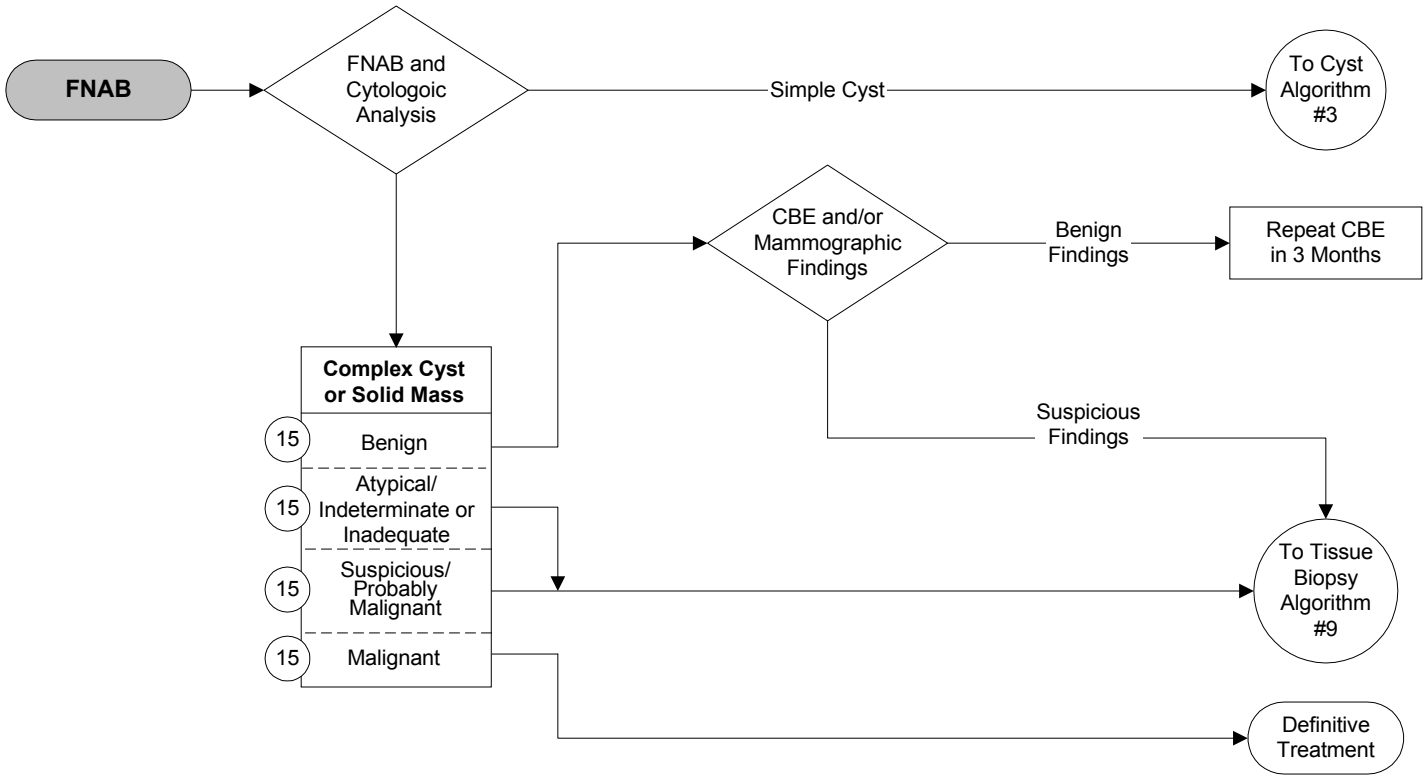
Triple Test

The "triple test" includes a clinical breast examination, mammography and non-surgical breast biopsy (FNAB or core biopsy) all performed within three months of each other. If all three procedures are interpreted as benign (concordant-benign), the lesion is followed without excision. If all three are concordant-malignant, definitive therapy is initiated without the intervening step. The triple test helps determine if further immediate work-up is needed. When the cytologic results from FNAB are combined with the mammographic and physical findings (triple test), over 95 percent of all breast cancers are detected and the accuracy of benign diagnoses is equivalent to that of histologic examination. The false positive rate of the triple test diagnosis is comparable to that of a frozen section.

Notes For Algorithm 8

(15) Breast FNAB adequacy is a controversial area and definitions will vary between laboratories. Cytologic definitions for the terms benign, atypical/indeterminate/inadequate, suspicious/probably benign, and malignant are included in the Appendix. For any inadequate result, the patient must be considered for further evaluation.

Management of Fine Needle Aspiration Biopsy Results for Breast Lesions



California Department of Health Services, 2000.

Management of Tissue Biopsy Results from Breast Lesions

Definitive diagnosis of a breast mass can only be established through FNAB, core needle, or excisional biopsy. Experts agree that if a mass persists for three months, a sampling of the lesion is warranted. Further delay in work-up is not prudent. Real-time sonography to guide interventional procedures is efficient and low-cost.

Breast biopsy techniques are grouped into two categories according to whether the mass is palpable or non-palpable.

Palpable masses

- Biopsy options for palpable masses include FNAB, large gauge needle core biopsy and excisional biopsy.
- FNAB extracts cells rather than tissue and has been described in the text for Algorithm 8.
- Core biopsies use a 14-18 gauge needle, usually in a spring-load instrument, to extract several cores of tissue (3-5mm incision). This technique is relatively simple, minimally invasive, and can be performed in a variety of outpatient settings.
- Excisional biopsy surgically removes an entire mass and a zone of tissue surrounding the mass. The procedure requires a sterile operating room setting and staff and leaves a small (2-4 cm) scar.

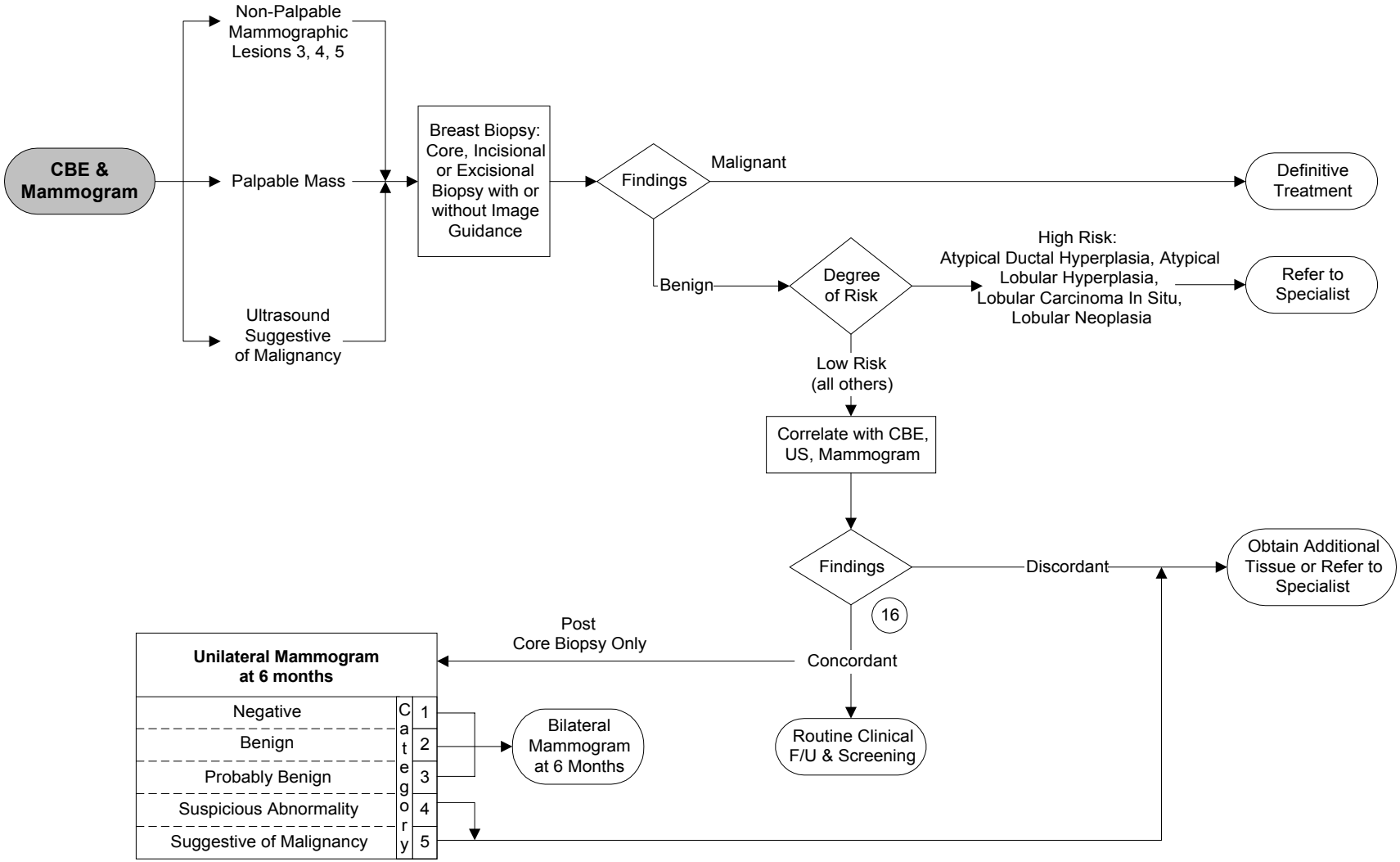
Non-palpable lesions

- Options for non-palpable lesions include needle-localization, ultrasound-guided localization and/or core biopsy, and stereotactic core biopsy.
- Needle localization involves inserting a guide wire through the lesion, which is verified through mammography, and then an excisional biopsy is performed. Following excision, specimen radiography is used to confirm lesion excision. Pathological analysis is performed to arrive at a diagnosis.
- Alternatively, ultrasound can be used as the imaging method by which physicians can either place a guide wire for excisional biopsy or use a core needle to obtain tissue.
- Stereotactic core biopsy is performed using a special mammography apparatus. The breast is compressed between two mammographic plates and the suspicious area is located by an imaging system. A core biopsy needle in an automated spring-loaded biopsy instrument is inserted into the lesion. Multiple biopsies are obtained. A physician with special skills is required to perform this procedure.

Notes for Algorithm 9

(16) Mammography can be performed using a radiopaque marker on the skin over a palpable lesion to help determine if the lesion corresponds to the mammographic lesion. A non-corresponding mammographic finding may represent a separate lesion that needs further work-up.

Management of Breast Tissue Biopsy Results



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APPENDIX

BREAST CLINICAL EXAMINATION PROCEDURES AND RATIONALES

The purpose of a clinical breast examination is to assess breast health status to determine an appropriate breast health program and a plan of action for each woman. This exam can be done as part of a general physical exam or gynecological exam or as a separate breast exam for asymptomatic or symptomatic women. The following components comprise a comprehensive examination.

PROCEDURE	RATIONALE
COMMUNICATION	
Introduce yourself and purpose of appointment Establish rapport Review health history and current symptoms (if any) Ask about comfort periodically during exam and make adjustments if needed Elicit and respond to questions/concerns	Communication has been shown to be a major determinant of patient satisfaction and perceptions of quality care; miscommunication and lack of patient understanding and agreement can result in noncompliance with recommendations, delayed diagnoses, and subsequent litigation.
POSITIONS **Patient Sitting** **Visual inspection (both frontal and lateral views)** arms at rest at sides arms held straight above head hands pressing down on hips with elbows bent, alternating downward pressure with relaxation (contracting pectoralis muscles) leaning forward (optional)	Conditions may not be apparent if only one position is used; inspect for changes or abnormalities in breast symmetry and contour, color, skin texture; nipple/areolar complex; skin retraction or dimpling (detection usually requires a sitting position to demonstrate).
Palpate breasts bimanually in sitting position <u>only if:</u> • woman found an abnormality in the sitting position	Not usually productive in sitting position except in these instances.

PROCEDURE	RATIONALE
and can't feel it when supine • portions of large pendulous breasts can be palpated better in this position • trying to palpate deep against the chest wall	
Patient Supine Centralize each breast on the chest wall (manually, sidelying maneuver, or pillow under shoulder) Place ipsilateral arm at right angle to head	Allows stability for palpation and better exposure of lateral aspects of breast, upper outer quadrant, and inframammary fold.
PERIMETER **Patient Supine** Trace outline of entire perimeter: (5 sided figure with 2 horizontal lines, 2 vertical lines, 1 diagonal line). Area includes: • clavicle superiorly • lateral edge of sternum medially • inframammary fold inferiorly • latissimus dorsi muscle laterally • distal clavicle to the edge of the lateral latissimus dorsi muscle at the lower axilla	Determine and demonstrate to patient entire area of breast tissue, especially those areas where cancers most commonly occur and areas which are most commonly missed (upper outer quadrant and axillary tail, retro–areolar complex, inframammary fold, along and under clavicle).
PATTERN OF SEARCH **Patient Supine** Use a consistent pattern you can perform confidently and thoroughly: • vertical strip, or • radial/wedge, or • concentric circles Pattern includes an adequate amount of overlap	Using the same pattern consistently will help assure that all breast tissue is palpated; pattern needs to be adequate to cover the perimeter borders and the area within the perimeter. Field tests and research have shown that vertical strip and radial/wedge patterns facilitate reaching the entire perimeter better than the circular pattern.

PROCEDURE	RATIONALE
PALPATION Use the fingers as pressure receptors 3 middle fingers of one hand pads, not tips hand bowed slightly upward sliding motion, without lifting fingers off the tissue slightly overlapping dime–size circles include nipple/areolar area (compress nipple gently in horizontal and vertical plane —only in the case of persistent history of spontaneous unilateral discharge)	Ascertain presence of asymmetrical thickenings, masses, or other abnormalities; for any abnormalities note: location, size, shape, consistency, texture, mobility, and tenderness; middle 3 fingers offer most sensitive pressure receptors and uniform surface area; size of circles may vary depending on finger width of examiner. When determining if a finding is asymmetrical, simultaneous palpitation of both breasts may be necessary.
PRESSURE Exert pressure using three sequential depths in spiraling dime–size circles at each palpation site • superficial circle (surface of the breast) • medium depth circle (middle structures) • deep circle (deepest tissues) Solicit feedback from patient on pressure	Using sequential pressure at each site allows optimal detection of asymmetrical thickenings or masses at different tissue depths; compression between the skin and chest wall maximizes the detection of discrete findings; soliciting patient feedback will reduce patient discomfort and reinforce technique for BSE.
PATIENT EDUCATION AND PLAN OF ACTION Point out breast tissue perimeter, anatomic landmarks, and different tissue types Reinforce BSE pattern and frequency Suggest appropriate intervals for early detection triad (CBE, mammography, BSE) based on patient's individual risk factors and unique needs Check for patient understanding and agreement	Principles of Breast Self Exam (BSE) are similar to CBE and the area for palpation is identical; women may learn best through observation of your CBE technique, their demonstration of the technique and your feedback; patient understanding of her own breast characteristics and agreement with recommendations may increase participation in regular screening examinations and increase motivation for prompt reporting of interval self–detected changes.

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Mammography

"0" **Incomplete Assessment:** *Need additional imaging evaluation***.**

Finding for which additional imaging evaluation is needed to determine a final category. This is almost always used in a screening situation and should rarely be used after a full imaging work-up. A recommendation for additional imaging evaluation includes the use of spot compression, magnification, special mammographic views, ultrasound, etc. Whenever possible, the present mammogram should be compared to previous studies. The radiologist should use judgment in how vigorously to pursue previous studies.

Assessment Is Complete — Final Categories

1 **Negative.** *Routine screening schedule is recommended*. There is nothing to comment on. The breasts are symmetrical. There are no masses, architectural disturbances or suspicious calcifications.

2 **Benign.** *Routine screening schedule is recommended*. This is also a negative mammogram, but the interpreter may wish to describe a finding. Involuting, calcified fibroadenomas; multiple secretory calcifications; fat-containing lesions such as oil cysts, lipomas, galactoceles; and mixed density hematomas all have characteristic appearances, and may be labeled with confidence. The interpreting physician might wish to describe intramammary lymph nodes, implants, etc. while still concluding that there is no mammographic evidence of malignancy.

3 **Probably Benign.** *Short Interval Follow-Up Suggested*. A finding placed in this category should have a very high probability of being benign. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability. Data are available that support the efficacy of short interval follow-up. At the present time, most approaches are intuitive. These will likely undergo future modification as more data accrue about the validity of an approach, the interval required, and the type of findings that should be followed.

4 **Suspicious.** *Biopsy should be Considered*. These are lesions that do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge biopsy. If possible, the relevant probabilities should be cited so that the patient and her physician can make an informed decision on a plan of action.

5 **Highly Suggestive of Malignancy.** *Appropriate Action Should be Taken*. These lesions have a high probability of being cancer and should lead to a timely tissue biopsy.

Note: These are equivalent to BI-RADS Categories 1-5.

Indications for Breast Ultrasound

1. Differentiation of cysts and solid masses
2. Evaluation of a palpable mass not visible in a radiographically dense breast
3. Evaluation of a mass that cannot be completely evaluated with mammography because of its location
4. Evaluation of a palpable mass in a young patient
5. Evaluation of an infected breast or an abscess
6. Guidance for interventional procedures.*

Ultrasound does not have a role in screening asymptomatic women of any age.

Ultrasound Findings

Sonographic differential diagnosis of solid breast masses is based on the following diagnostic categories. The criteria for identifying benign versus malignant lesions are constantly being updated as equipment and technology advances. Some examples of benign and malignant classifications are included, with the benign ones listed first within the parentheses (benign; malignant).

- Shape: (round/oval; irregular, jagged)
- Geometry: (flat; high, length/width>1)
- Contour: (sharp—encapsulated; diffuse)
- Tumor front
- Interval echo strength
- Interval echo distribution (uniform; heterogeneous)
- Absorption
- Refraction
- Elasticity
- Mobility: (surrounding tissue glides over lesion; lesion is fixed)
- Relation to palpation
- Relationship to surrounding tissue**

*From Jackson VP. Breast sonography. pg. 192. *Bassett LW. Diagnosis of Diseases of the Breast.* Philadelphia, WB Saunders, 1997.

**From Sickles E. *Radiological Diagnosis of Breast Diseases*. New York. Springer Verlag. 1997

The following benign pathologic conditions do not show any significant increased risk for the subsequent development of invasive breast cancer and would be considered to be a negative finding on needle core biopsy or surgical excision:

Fibroadenoma: A focal well-circumscribed growth of glands and stroma in which proliferating stroma surrounds the growing glands and often compress and distort them.

Fibrocystic change: A benign condition representing focal, non-uniform changes in the breast tissue representing a wide variety of pathologic changes that can consist of any combination of the following:

Adenosis: A benign proliferation of glandular acini within a lobule.

Apocrine metaplasia: A benign change in which the epithelium of ducts and lobules change to a cell type similar to those of apocrine sweat glands and is frequently seen in cysts.

Duct ectasia (cysts): A dilatation of medium to large ducts lined by flattened cells, filled with amorphous debris, and associated with periductal inflammation.

Epithelial hyperplasia: A increased proliferation of cells lining the ductal-lobular unit which distend the glandular space. The cells are variable in appearance, maintain their polarity and form irregular, slit-like spaces.

Fibrosis: increased collagen deposition within the breast stroma.

Papillomas: Frond- or finger-like growths with a fibrovascular core which is always associated with epithelial hyperplasia of varying degrees. Can occur in large or small ducts and can be solitary or multiple.

Papillomatosis: Multiple, small papillomas.

Sclerosing adenosis: A benign proliferation of acini within a lobule associated with fibrosis and distortion of the lobule.

The following pathologic conditions show significant increased risk for the subsequent development of invasive breast cancer and would be considered to be a high-risk finding on needle core biopsy or surgical excision:

Atypical ductal hyperplasia (ADH): A proliferation of cells confined to the ductal-lobular space which has some but not all of the features of ductal carcinoma in-situ and is characterized by a population of evenly spaced uniform cells with monotonous hyperchromatic nuclei which form the rigid geometric structures similar to ductal carcinoma in-situ (DCIS), but only involves part of the membrane-bound ductal-lobular space. This finding indicates a moderately increased risk of invasive breast cancer, which is five times above that of the general population.

Lobular neoplasia: A term used to represent the spectrum of changes which include atypical lobular hyperplasia and lobular carcinoma in-situ which some pathologists may prefer due to controversies on criteria for differential diagnosis of the two lesions.

Lobular carcinoma in-situ (LCIS): Characterized microscopically by distention of at least half of the acini in a lobular unit by a very round uniform population of small cells which may have clear cytoplasm or nuclear vacuoles. Usually an incidental finding in breast tissue removed for another indication, frequently multi-focal and bilateral, and rarely causes clinical findings or changes on a mammogram. This finding indicates an increased risk of invasive breast cancer which is ten times above that of the general population.

Atypical lobular hyperplasia (ALH): A proliferation of cells confined to the ductal-lobular space which has some but not all of the features of lobular carcinoma in-situ and is characterized by a population of bland, round cells which are evenly spaced and often of smaller size than those seen in ADH or DCIS. These cells resemble those of lobular carcinoma in-situ, but do not completely fill and distend the glandular acinus leaving intercellular spaces, or involve less than half of the multiple acini in a lobular unit. This finding indicates a moderately increased risk of invasive breast cancer, which is five times above that of the general population.

The following conditions are non-invasive malignancies:

Ductal carcinoma in-situ, comedo type: Distended ducts and lobules lined by an increased number of large cells with pleomorphic nuclei of high grade and which contain central necrotic debris which grossly resemble the center of a comedone and which can calcify and can appear mammographically as coarsely granular or "casting" calcifications outlining the involved duct. The size of this type of DCIS is frequently underestimated mammographically and can be quite extensive. This finding indicates an increased risk of invasive breast cancer, which is ten times above that of the general population.

Ductal carcinoma in-situ, non-comedo type: Includes those forms of ductal carcinoma in-situ that are classified as micropapillary, cribriform solid, or clinging and are characterized by distension of the involved ducts and lobules by smaller, uniform, monotonous cells which do not have the high nuclear grade typical of the cells of comedo-type of DCIS. There is no central necrosis, and the abnormal cells often create rigid geometric spaces and bridges within the involved duct/lobule. This type can also appear as microcalcifications by mammography, though less frequently than the comedo-type, and usually appears as fine granular calcifications. This finding indicates an increased risk of invasive breast cancer, which is ten times above that of the general population.

The following pathologic conditions represent malignant tumors and would be considered to be a positive cancer finding on needle core biopsy or surgical excision:

Infiltrating ductal carcinoma: The most common type of invasive breast cancer, accounting for as many as 75-80 percent of all breast cancers and are sometimes also referred to as carcinoma of no special type. These tumors can vary microscopically in their degree of tubule formation, mitotic rate, and nuclear pleomorphism and grading these features can give a clue to prognosis. There are several special types of ductal carcinoma which are all considered to have an improved survival rate than those of no special type.

Infiltrating lobular carcinoma: Characterized histologically by small cells which frequently contain a cytoplasmic vacuole which are classically arranged in a single-file "Indian-file" arrangement. The stroma is densely sclerotic giving this tumor a rock-hard feeling to palpation and making the cells difficult to remove by fine needle aspiration. This tumor has an intermediate prognosis in its classic form (variants do exist), and has an increased incidence of multi-focality and bilaterality.

Medullary carcinoma: Characterized histologically by syncytial sheets of large extremely pleomorphic cells with a prominent lymphoid infiltrate. Usually well circumscribed with little fibrous reaction; can feel deceptively soft and benign.

Mucinous (colloid) carcinoma: A well-differentiated form of ductal carcinoma, accounts for two percent of all breast cancers, is more common in older women, usually well-circumscribed, and is characterized by the production of abundant pools of mucin making it deceptively soft and benign.

Papillary carcinoma: Usually occurs in larger ducts which can be cystically dilated, and resembles the frond-like branching structure of the benign papilloma, but is lined by atypical cells.

Tubular carcinoma: The most well-differentiated form of ductal carcinoma, frequently presenting as small occult lesions discovered by screening mammography, and usually curable. Derives its name from well-defined oval or round tubular structures formed by cells with little atypia.

Malignant phyllodes tumor: Formerly called cystosarcoma phyllodes characterized by a proliferation of benign glands and malignant stroma with more than 10 mitoses per high field which may resemble fibrosarcoma or have heterologous elements such as malignant bone cartilage, skeletal muscle or fat. Unlike carcinomas, these metastasize hematogenously and can spread along nerves.

CYTOLOGIC DEFINITIONS

The following terminology has been recommended by the National Cancer Institute sponsored conference on September 9-10, 1996 for use in findings from fine needle aspiration biopsy of the breast. Each category should be further described and classified as appropriate with an attempt to place the findings into a specific pathologic diagnosis.

Benign: No evidence of malignancy; includes fibrocystic change without atypia, fibroadenoma, pregnancy-or treatment-associated changes, infectious and inflammatory conditions.

Atypical/Indeterminate: Probably benign, but a definitive diagnosis cannot be provided due to either technical difficulties such as limited cellularity or poor preservation, or due to the inherent nature of certain breast lesions such as papilloma vs. papillary carcinoma, fibroadenoma vs. phyllodes tumors, proliferative lesions with atypia vs. in-situ or low-grade infiltrating carcinomas.

Suspicious/Probably Malignant: Highly suggestive of malignancy, but a definitive diagnosis cannot be made due to either technical difficulties such as limited cellularity or poor preservation, or due to the inherent nature of certain breast lesions such as papilloma vs. papillary carcinoma, fibroadenoma vs. phyllodes tumors, proliferative lesions with atypia vs. in-situ or low-grade infiltrating carcinomas.

Malignant: Diagnostic of malignancy and should be further characterized with the specific type of neoplasm such as ductal or lobular carcinoma.